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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/802,400 | 03/17/2004 | Gerard Marx | 39612/20 | 3706 |
| 1912 | 7590 | 01/11/2007 | | EXAMINER |
| AMSTER, ROTHSTEIN & EBENSTEIN LLP | | | | NAFF, DAVID M |
| 90 PARK AVENUE | | | | |
| NEW YORK, NY 10016 | | | | |
| | | | ART UNIT | PAPER NUMBER |
| | | | | 1657 |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | | DELIVERY MODE |
| 3 MONTHS | | 01/11/2007 | | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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|------------------------------|-----------------|--------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/802,400 | MARX ET AL. | |
| | Examiner | Art Unit | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 March 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 50-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 50-69 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 17 March 2004 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/28/04, 3/17/04
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

A preliminary amendment of 3/17/04 amended the specification and a preliminary amendment of 7/28/04 amended the specification, and amended the claims by canceling claims 1-49 and adding new claims 50-

5 69.

Claims examined on the merits are 50-69, which are all claims in the application.

Double Patenting

The nonstatutory double patenting rejection is based on a 10 judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the 15 conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

25 A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of 30 activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

35 Claims 50-69 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,737,074 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other

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because the presently claimed wound healing composition and tissue forming composition would have been obvious from the method of the patent claims where claims 4-7 require wound healing cells combined with fibrin microbeads that are the same as the microbeads required by 5 the present claims. Wound healing cells in claim 5 of the patent are cells capable of forming tissue, and the presently claimed tissue forming composition would have been obvious from the patent claims requiring wound healing cells.

Double Patenting

10 Claims 50-69 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,503,731 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed wound healing composition and tissue 15 forming composition would have been obvious from composition claims of the patent that require cells (claims 7-30), which can be cells capable of wound healing and forming tissue (claim 11) in combination with fibrin microbeads that are the same as the fibrin microbeads of the present claims.

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Double Patenting

Claims 50-69 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,150,505 or claims 1-16 of U.S. Patent No. 6,552,172 B2 in view of Marx (5,411,885) and Berneman et al 25 (4,373,027).

Marx discloses culturing tissue embedded in fibrin glue made from fibrinogen, fibrinogen-activating enzyme and a calcium compound.

Berneman et al disclose culturing cells capable of forming tissue on microparticles. The microparticles can be made of a protein of the 5 fibrinogen type (col 2, lines 43-45).

It would have been obvious to form wound healing and tissue forming compositions by combining wound healing and tissue forming cells with the fibrin microbeads of the claims of the patents in view of Marx embedding and culturing tissue in fibrin glue and Berneman et 10 al culturing cells capable of forming tissue on microparticles made of fibrinogen. Cells capable of wound healing may also form tissue, or the converse.

Conclusion

Any inquiry concerning this communication or earlier 15 communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. 20 The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for 5 unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer 10 Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



David M. Naff
Primary Examiner
Art Unit 1657

DMN

15 1/6/07